

### **REMARKS/ARGUMENTS**

Claims 17 and 19-57 are pending in this Application. The Office Action mailed on January 16, 2008 included the following rejections:

1. Claims 42-46 are rejected under 35 U.S.C. § 112 Second paragraph.
2. Claims 47-52 and 55 are rejected under 35 U.S.C. § 112 Second paragraph.
3. Claims 17, 21-25 and 34-41 were rejected under 35 U.S.C. § 103.
4. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.
5. Claims 17, 19-47 and 49-57 stand rejected under the nonstatutory, judicially created doctrine of double patenting.

Applicant respectfully addresses the basis for each of the rejections below.

#### ***Claim Rejections – Claims 42-46 are rejected under 35 U.S.C. 112 Second paragraph.***

The Action rejects claims 42-46 under 35 U.S.C. § 112 Second paragraph. Specifically stating that the use of “...provides relief to patients” is indefinite as the term provide relief is not defined by the claim. Applicants submit that the claims are not indefinite and the skilled artisan recognizes how relief can be measured.

It is not necessary for the Applicant to specifically state how relief may be measured to comply with 35 U.S.C. § 112 Second paragraph as such knowledge is within the scope of the knowledge of the skilled artisan. The Examiner is reminded that the courts have held that it is not necessary to specify the dosage or how relief may be measured as it is known to one skilled in the art and such information can be obtained without undue experimentation. For example, it is not necessary for the application to state specifically what the exact amount to be administered to each and every patient, as that is within the scope of the knowledge of the skilled artisan. Since a statement of utility in the specification contains within it a connotation of how to use the present invention and the art recognizes that standard modes of administration are known and

contemplated, 35 U.S.C. § 112 is satisfied, e.g., see *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993). Specifically, it is not necessary to specify the dosage or how relief may be measured as it is known to one skilled in the art and such information can be obtained without undue experimentation. One skilled in the art, based on knowledge of compounds and treatments having similar physiological or biological activity, would be able to discern an appropriate dosage or how relief may be measured without undue experimentation, and as such is sufficient to satisfy 35 U.S.C. § 112.

Therefore, Applicants submit that the claims are not indefinite and respectfully request withdrawal of the rejection.

***Claim Rejections – Claims 47-52 and 55 are rejected under 35 U.S.C. § 112 Second paragraph.***

The Action rejects claims 47-52 and 55 under 35 U.S.C. § 112 Second paragraph. Applicants submit that claims 47-52 and 55 as amended fully comply with 35 U.S.C. § 112 Second paragraph. As such, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112 Second paragraph.

***Claim Rejections – Claims 17, 21-25 and 34-41 are rejected under 35 U.S.C. § 103.***

The Action rejects claims 17, 21-25 and 34-41 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent Number 6,225,347 (“Buchmann” et al.) in view of Iwama, et al. (“Iwama”). Applicants respectfully submit that claims 17, 21-25 and 34-41 are not obvious over the cited art and is, therefore, allowable under 35 U.S.C. § 103(a) for the reasons stated below.

Buchmann merely relates to 9-halogen-(Z) prostane derivatives and Iwama to acute myocardial infarction due to coronary embolism. The combination does not teach a method for

treating a patient in need of treatment for a cardiac disorder, comprising administering to said patient an effective amount of a n-heptanoic acid composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy.

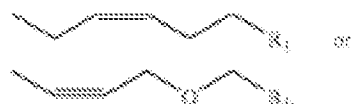
Buchmann is non-enabling art and cannot be combined with Iwama to teach each and every limitation of the present invention. To establish a *prima facie* case of obviousness there must be: (1) some suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) a reasonable expectation of success, and (3) a teaching or suggestion in the prior art reference of all of the claim limitations (MPEP § 2143). *In re Vacek*, 947 F. 2d. 488 (Fed. Cir. 1991).

First, the combination simply does not teach or suggest all of the claim limitations. Buchmann DOES NOT teaches an n-heptanoic acid composition. Buchmann teaches a prostaglandin composition, see the title “9-halogen-(Z)-prostaglandin derivatives, process for their production and their use as pharmaceutical agents” and throughout Buchmann. As stated above, Buchmann merely discloses a prostaglandin, which contains 20 carbon atoms, including a 5-carbon ring as does every prostaglandin by definition. Buchmann defines the invention in formula I (for convenience presented below):

The invention relates to 9-halogen-(Z) prostaglandin derivatives of the formula I



in which  $Z$  represents the radicals



The specification does include the words “heptanoic acid” in column 3, line 22. However, Buchmann **does not** disclose an **n-heptanoic acid composition**. When taken in the intended

context of the specification of Buchmann and not merely looking for the use of the term, it is clear that the "heptanoic acid" is a part of the prostaglandin in Buchmann and not an n-heptanoic acid composition. In Buchmann, column 3, lines 11-22 (see below) the compounds listed in that paragraph (column 3, lines 11-49) are "suitable acid radicals."

Suitable as acid radicals are physiologically compatible acid radicals. Organic carboxylic acids and sulfonic acids with 1-15 carbon atoms are suitable, which belong to the aliphatic, cycloaliphatic, aromatic, aromatic aliphatic and heterocyclic series. These acids can be saturated, unsaturated and/or polybasic and/or substituted in a conventional manner. Alkyl, hydroxy, alkoxy, oxo or amino groups or halogen atoms can be mentioned as examples for the substituents. For example, the following carboxylic acids can be mentioned: formic acid, acetic acid, propionic acid, butyric acid, isobutyric acid, valeric acid, isovaleric acid, caproic acid, heptanoic acid, caprylic acid, pelargonic acid,

Therefore, given the disclosure of Buchmann it is clear that any heptanoic acid is used to form the prostaglandin and NOT a n-heptanoic acid composition. The addition of Iwama to Buchmann in NO way cures the deficiencies. The combination does not teach a n-heptanoic acid composition.

Even if the combination did teach each and every limitation of the present invention, (which it clearly does not) the combination would still not render the present invention obvious under 35 U.S.C. § 103(a) because there is NO suggestion or motivation either in the reference itself, or within the knowledge generally available to one of ordinary skill in the art, to modify the reference and NO reasonable expectation of success. The proposed modification of the combination renders invention being modified unsatisfactory for its intended purpose.

MPEP Section 2143.01(V) states that "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." Likewise, MPEP Section 2143.01 (VI) states "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious."

The proposed modification/combination of the prior art change the principle of operation

of the prior art invention being modified, in such a manner to render it unsuitable for use as a method for treating a patient in need of treatment for a cardiac disorder by administering to said patient an effective amount of a n-heptanoic acid composition to provide relief to said patient from said cardiac disorder selected from cardiac muscle weakness or cardiac myopathy. Specifically, prostaglandins act in a different manner and serve a very different function. For example, prostaglandins are mediators and have a variety of strong physiological effects; although they are technically hormones, they are rarely classified as such.

Furthermore, the combination does not serve the same function as stated in Buchmann the compositions are used to compounds are effective in lowering blood pressure, unlike the present invention. See (column 11, lines 1-10):

Some of the compounds are effective in lowering blood pressure, in regulating cardiac dysrhythmia and in inhibiting platelet aggregation with the resulting possibilities of use such as, e.g., in coronary heart disease and myocardial infarction. The new prostaglandins can also be used in combination, e.g., with beta-blockers, diuretics, phosphodiesterase inhibitors, calcium antagonists, thromboxane antagonists, thromboxane synthetase inhibitors and cyclooxygenase inhibitors, anticoagulant substances such as fibrinolytic agents, leukotriene antagonists, leukotriene synthetase inhibitors and antigestagens.

Therefore the combination of Buchmann and Iwama fail on all counts to establish a *prima facie* case of obviousness (i.e., there is no suggestion to modify the reference, no reasonable expectation of success and no teaching of all of the claim limitations. As such, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

***Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over claims 25-27, 37-40, 42-45 and 47-56 of U. S. Patent Application No.10/371,385.***

The Examiner states the subject matter claimed in the instant application is fully disclosed in the patent application since the patent and the application are claiming common subject matter. A terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed upon

notice of allowable claims in either application to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent applications are shown to be commonly owned with this application. See 37 CFR 1.130(b).

***Claims 17, 19-47 and 49-57 stand provisionally rejected under the nonstatutory, judicially created doctrine of double patenting over claims 15-18 and 21-36 of U. S. Patent Application No.10/748,732.***

It is unclear how application 10/748,732 entitled, "Access Circuit and Method for Allowing External Test Voltage to be Applied to Isolated Wells" has to do with the present invention. Specifically, claims 5 and 15 listed below. For the reasons mentioned above, the Applicants respectfully request the withdrawal of the rejection.

15. The access circuit of claim 5 wherein the second control circuit comprises:

a shunt transistor having a gate terminal and a pair of source-drain terminals coupled between the externally accessible terminal and the gate electrode of the second transistor; and

a control transistor having a gate terminal coupled to receive the second access signal, the control transistor having a pair of source-drain terminals coupled between the externally accessible terminal and the gate terminal of the shunt transistor.

**Conclusion**

In light of the remarks and arguments presented above, Applicant respectfully submits that claims 17, 19-47 and 49-57 are pending in this application and claims 18 and 48 have been cancelled. Applicant submits that this application are in condition for allowance. Favorable consideration and allowance of the pending claims are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: February 27, 2008.

Respectfully submitted,



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